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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,790

04/08/2005

Hideko Kosaka

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7590

08/19/2009

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EXAMINER

WHITE, DENNIS MICHAEL

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

08/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,790	Applicant(s) KOSAKA, HIDEKO	
	Examiner DENNIS M. WHITE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Arguments filed on 5/27/2009 are noted. Currently claims 1-8, 12-16 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-8, 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al (Chem. Pharm. Bull 1983), hereinafter "Mori", in view of Kosaka (US 2002/0037591).

Regarding claims 1-2, 7-8, 12-15, Mori teaches reagents for a spectrophotometric determination of creatinine ("test for creatinine measurement comprising") comprising a color indicator 0-hydroxyhydroquinonephthalein, hereinafter "Qn.Ph." and palladium(II) that forms a complex together. The Qn.Ph. solution is 0.001 mol/liter, palladium(II) is 0.0005, therefore the ratio is 2:1 and has been read on claim 12. The test further comprises a buffer solution of 0.2M acetic acid and 0.2M sodium acetate. The ratio is 1:200 of indicator to buffer and has been read on claim 14 (Pg. 1389). Mori teaches the test further comprises surfactants of 1.0mL of 1.0% PVA and 1.0mL of 1.0% SDS in a total volume of 10mL. Mori is silent that the reagents are on a test piece, the compound is in a porous material, and the color indicator is pyrocatechol violet, chromazurol S, or chromazurol B, and the compound to surfactant molar ratio is 50:1 to 3:1.

Kosaka teaches a composition for detecting trace amount of protein comprising an indicator reagent and a transition element. The indicator reagent and the transition

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element form a complex that then is used to show a color change indicating the presence of a protein. (Abstract) The reagent composition is suited for the measurement under wet conditions as a liquid reagent and also under dry conditions in which the reagent composition is uniformly incorporated into a carrier comprising water-absorbable porous materials such as filter paper. It is desirable to provide the reagents on a carrier with porous materials because it allows for the reagent composition to be included in the carrier uniformly over its entire portion at predetermined concentrations so that the liquid protein concentration can accurately be determined (Para. 0023). The indicators dye that are known to form a complex with a transition metal that binds to a protein to shift the wavelength comprise dyes such as pyrocatechol violet ("formula (1)" "formula (2)" and "formula (7)") and o-hydroxyhydroquinone phthalein or "Qn.Ph" (Para. 0025). Kosaka teaches the surfactant can be in an amount of the surfactant in the reagent composition from about 0.001 to 1% by weight.

Therefore it would have been obvious to one of ordinary skill in the art, as motivated by Kosaka, to provide the reagents of Mori in the porous material carrier of Kosaka in order to for the reagent composition to be included in the carrier uniformly over its entire portion at predetermined concentrations so that the liquid protein concentration can accurately be determined.

Simple substitution of one known element for another to obtain predictable results is held to be obvious. Therefore it would have been obvious to one of ordinary skill in the art to substitute the Qn.Ph. of Mori with the pyrocatechol violet of Kosaka in order to provide a well known indicator capable of forming a complex with a transition

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metal ion that binds to an analyte to shift the wavelength and be able to detect trace amounts of the analyte.

Regarding claims 3-6, Mori/Kosaka teach the compound pyrocatechol violet (formula 7). Mori/Kosaka are silent about the compound is Chromazurol S (formula 3 and 4), Chromazurol B (formula 5), and Eriochrome cyanine (formula 6). Structural similarities have been found to support a prima facie case of obviousness. See, e.g., In re May, 574 F.2d 1082, 1093-95, 197 USPQ 601, 610-11 (CCPA 1978) (stereoisomers); In re Wilder, 563 F.2d 457, 460, 195 USPQ 426, 429 (CCPA 1977) (adjacent homologs and structural isomers); In re Hoch, 428 F.2d 1341, 1344, 166 USPQ 406, 409 (CCPA 1970) (acid and ethyl ester); In re Druey, 319 F.2d 237, 240, 138 USPQ 39, 41 (CCPA 1963) (omission of methyl group from pyrazole ring). Generally, some teaching of a structural similarity will be necessary to suggest selection of the claimed species or subgenus. See also In re Hoeksema, 399 F.2d 269, 158 USPQ 596 (CCPA 1968) (A claim to a compound was rejected over a patent to De Boer which disclosed compounds similar in structure to those claimed (obvious homologs) and a process of making these compounds).

Therefore, it would have been obvious to one of ordinary skill to substitute chromazurol B, chromazurol S, and Eriochrome cyanine R as known equivalents of or pyrocatechol violet to obtain the expected result of indicators capable of color changes.

Regarding claim 16, Mori and Kosaka fail to teach the claimed ratio of compound to surfactant. In re Boesch (205 USPQ 215) teaches the optimization of a result

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effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The choice of a surfactant is a result effective variable that gives the well known and expected results of managing the surface characteristics of the reactants. It is desirable to provide surfactant at levels that increase the reactivity without interfering with protein measurement (Kosaka: Para. 0031).

Therefore it would have been obvious to provide the ratio of compound to surfactant in the ratio of 50:1 to 3:1 in order to provide an amount of surfactant to increase the reactivity without interfering with the measurement and as optimization of a result effective variable.

Response to Arguments

4. Applicant's arguments filed 5/27/2009 have been fully considered but they are not persuasive.

5. Applicants argue that the detection mechanisms of Mori and Kosaka are completely different because Mori is directed to addressing analytical non-specificity of a non-protein waste product and Kosaka is directed at measuring protein in a liquid sample such as urine. It is noted that Mori and Kosaka are using an indicator and a metal to detect the presence of an analyte in urine. Furthermore, Kosaka teach the equivalence of pyrocatechol violet and Qn-Ph, therefore the substitution of the known indicators is proper.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

/dmw/